



Saalux[®]

User Manual

User manual

Saalux[®] UV comb

UV comb (UVB 311nm) UK



CE₀₁₂₃

We thank you for your confidence in Saalman[®] therapy devices.

You made a wise choice: the Saalio[®] UV comb has been designed to combine maximum benefit with ease of use. It is easy to set up and simple to operate. This user manual will guide you through the setup procedure, familiarize you with its functions and offer advice and tips on the use of your new therapy system.

Please review this user manual carefully!

Content

1 Scope of Delivery	4
2 Accessories and Spare Parts	4
3 Safety Information	4
4 Key to symbols	7
5 Proper Use	8
6 Basic Information on UV Phototherapy	8
7 Intended Purpose and Indications	9
8 Contraindications, risks and side effects	9
9 Initial Operating Instructions	11
10 Therapy Recommendation	11
11 Cleaning and Disinfection	18
12 Transport and Storage	19
13 Errors and Troubleshooting	19
14 Life cycle and service life	19
15 Maintenance and Repair	20
16 Warranty	20
17 Electromagnetic compatibility	20
18 Spectral Distribution of the Flow of Radiation	21
19 Technical Data	21
20 Disposal instructions	22
21 Manufacturer contact information	22
Appendix 1 – Electromagnetic compatibility	23
Appendix 2 – Patient diary	25

1 Scope of Delivery

The set consists of the therapy device with UV lamp and comb attachment, small UV protective goggles, count-down timer and a user manual.

2 Accessories and Spare Parts

Large UV protective goggles (for wearer of glasses)	Item No. 07-02-019-01
Comb attachment	Item No. 07-02-005-01
User manual UK	Item No. 07-02-001-02
Small UV-protective goggles	Item No. 07-02-002-01
Count down timer	Item No. 07-02-003-01

3 Safety Information



„Caution“ safety information: this sign precedes important notices in the user manual.



The therapy device may only be used for the indications specified in this user manual.



The therapy device may only be used for the „intended use“ specified in this user manual. Any use beyond the defined scope is considered „not as intended“ and will immediately render the warranty void. The manufacturer accepts no responsibility for personal injury or damage to property resulting from „not as intended“ use.



The therapy device may only be used when in proper condition and with the original accessories.

The device may not be altered.

If the power cord is damaged, you must have it replaced by Saalman to avoid the risk of electric shock.



The therapy device may only be operated in dry rooms and in the temperature range stated in this user manual.



Water and electricity are a dangerous combination! To avoid risk of electrocution:

- do not use this equipment in wet surroundings (e.g. in the bathroom or near a shower or swimming pool),
- do not let water run into the appliance.



The use of this device next to other equipment should be avoided, as it may result in improper operation. If use in the manner described above should nevertheless be necessary, this equipment and the other equipment should be checked for proper operation.



This device emits UV radiation through the transparent comb attachment, which can cause eye or skin irritation. Avoid the UV radiation of eyes and healthy skin. The UV radiation is not visible for the human eye and can lead to corneal inflammation (photokeratitis) and eye inflammation (photoconjunctivitis) within a short time.

It is imperative that during a therapy session, you wear the UV protective goggles included in the scope of delivery. Also, avoid looking into the UV lamp with unprotected eyes; immediately switch off the therapy device after treatment and also during short-term interruptions in the treatment session.



Never operate the device without comb attachment.



UV-radiation can cause the skin burn within a short period of time. It is imperative that you pay attention to the therapy recommendations specified in the user manual.



To avoid erythema (sun burn), healthy skin (e.g. ears) must be protected with a high protection factor sun cream, which is to be applied to those areas in due time before the treatment session (see page 8)



The intensive use of the therapy device over years can promote the development of skin cancer. Avoid excessive sun exposure during the treatment cycle; also, adjust your leisure behaviour during this time. You should not visit tanning studios while using the device in a treatment cycle.



This device is not intended for use by persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the equipment to avoid the risk of fire or burns.



This device is not intended for independent use by children. The treatment of children is carried out exclusively by adults. Children should be supervised to ensure that they do not play with the equipment to avoid the risk of fire and burns.



Do not leave the device unattended when it is switched on to avoid the risk of fire or burns.



Check if the voltage indicated on the device corresponds to the local mains voltage before you connect the equipment to avoid risk of electrocution or permanent damage to the device.

If the wall outlet used to power the device has defective connections, the plug of the device will heat up. Make sure that the plug of the device is inserted into a properly installed wall socket to avoid the risk of fire or burns.

Make sure that you can unplug the power cord from the wall outlet at any time.



Always unplug the device after use and in case of a power failure to avoid risk of damage to the equipment.



Protect the device against unauthorized use:

- unplug the AC adapter from the socket immediately after use,
- store the device securely so that unauthorized persons cannot access the device (e.g. by locking it away).

Do not use it near children and never leave the device unattended (Danger of UV exposure and strangulation).



Do not subject the equipment to heavy shocks to avoid risk of damage to the lamp.



RF communications equipment (radios) and their accessories should not be used within 30 cm of the components and cables of the Saalux® UV Comb. Observe the recommended EMC protective distances in Appendix 1. Failure to do so may lead to a reduction in the performance of the device.

4 Key to symbols

Symbols in the user manual and on the unit:



Caution:
Important note!



Caution:
Ultraviolet radiation!



Do not stare at light
source!



Wear UV protective
goggles!



Read the user
manual!



Type BF applied part



Keep dry!



Medical Device



Manufacturer's CE-
declaration with no. of
Notified Body



Manufacturer



Item No.




Batch Code



Class II equipment



Disposal instructions:
Do not dispose of the
equipment with
domestic waste!

Risk Group 2	
	WARNING! UV emitted from this device. Eye or skin irritation may result.
Product tested against DIN EN 62471: 2009	

5 Proper Use

The unit is intended to be used in closed rooms. Allow the unit to reach room temperature before conducting a treatment. The device may only be used in a dry environment. The required minimum distance to shortwave microwave devices depends on their frequency and transmission power and is defined in the EMC tables (see attachment 1). For additional information, please refer to item 9 in the operating instructions.

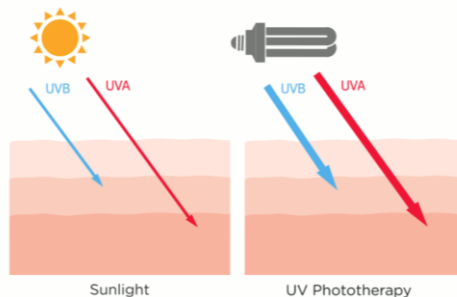
At the start of the therapy, approx. 3 - 5 treatments per week are to be conducted. Exposure time depends on the patient's individual sensibility and skin type. Special care has to be taken to exceeding the erythema threshold (development of sun burn). We refer to the specific instructions in this user manual. Due to the intermittent appearance of clinical symptoms, an according maintenance therapy in a domestic setting is indicated.

The treatment is conducted based on a doctor's recommendation and in accordance with the treatment guidelines laid down in the user manual. Any use beyond this scope is considered „not according to proper use“. The manufacturer cannot accept any responsibility for personal injury or material damage that is or might be caused by usage beyond the scope of „proper use“.

6 Basic Information on UV Phototherapy

UV phototherapy is an established procedure, recognized for decades for the treatment of various skin diseases, particularly psoriasis, neurodermatitis and vitiligo. UV radiation affects the upper skin cells and, after repeated application, positively influences the immune system

and the skin's regeneration behaviour. The UV-B 311nm narrowband spectrum emitted by the UV comb is a highly selective spectral range of natural sunlight, which is therapeutically effective while causing few side effects.



7 Intended Purpose and Indications

The Saalux® UV comb is used for radiation therapy of minor skin lesions in the form of scaly, inflammatory or disfiguring skin diseases. The UV radiation leads to healing of the skin lesions and improvement of the general skin appearance. The treatment is applied to persons suffering from **plaque psoriasis, vitiligo or neurodermatitis** on the scalp or other limited skin areas. Please note the contraindications under item 8.

The device can also be used by lay persons and does not require training or separate instruction. Only start the treatment after you have carefully read and understood the entire instructions for use. In case of any uncertainties, contact the manufacturer or the attending physician.

The treatment of children and adolescents may only be performed by an adult. If the treatment is carried out by a second person, the contraindications, risks and side effects as well as the safety instructions regarding UV protection also apply to this person.

8 Contraindications, risks and side effects



The UV therapy must not be applied in case of:

- Increased sensitivity to light or an increased risk of skin cancer
- History of malignant skin tumors
- Severe actinic skin damage
- Medicines, foods or cosmetics that may lower the erythema threshold or react in a harmful way in combination with UV radiation
- concomitant drug treatment with potential skin damage
- Seizure disorders
- Small children (up to 6 years)



Risks and long term side effects:

- Phototoxic reactions
- Provocation of light dermatoses (PLD)
- Photoaging of the skin
- UV lentiginos (age spots)
- Hyperpigmentation of healthy skin areas (Vitiligo)
- Conjunctivitis and keratitis (lack of eye protection)



The following acute side effects can occur:

- Erythema (sunburn)
- Blistering (severe erythema)
- Dry skin
- Itching

9 Initial Operating Instructions

The device may only be used with a power supply that matches the supply voltage specified on the rating plate. To ensure safe operation of the unit, all its cables, plugs, control elements, and housing components must be in faultless condition. Prior to each use, check the device for possible damage; a defective unit may not be operated. Visible dirt on the transparent comb attachment must be removed following the cleaning instructions. Pay attention to the references on the unit and in the user manual. Please switch the unit off after you finished a treatment session.

10 Therapy Recommendation

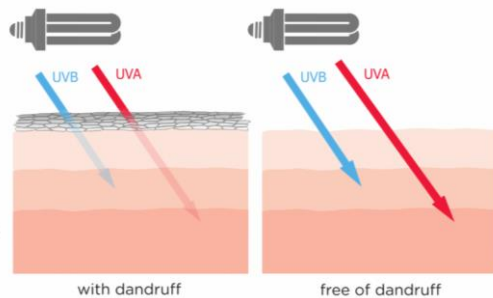
Basic operation:

The applied UV dose is controlled by the treatment duration of a therapy session. The treatment duration is to be increased until a slight reddening of the skin (mild sunburn or erythema) occurs with some delay, which has subsided after 24 hours at the latest. This so-called erythema threshold is different for each user and determined by the individuals' skin type. At the beginning of the therapy, always start with low treatment durations, which are then gradually increased from session to session until the erythema threshold is reached.

During UV irradiation, the comb attachment should rest on the skin to ensure a constant irradiation intensity during the application. For the treatment of a larger skin area (e.g. scalp), the treatment time should be increased accordingly. The UV comb should then be moved evenly over the entire area with the comb attachment resting on it.

Removing dandruff:

Plaques and scales absorb the UV radiation and prevent the UV radiation from penetrating into the diseased skin layers. In case of extensive manifestations, thoroughly remove plaques and scales before starting the UV therapy (e.g. with the Saalux® dandruff solution, see page 29).



UV protection

Prior to starting the treatment, healthy skin areas (the ears, amongst others) should be covered or creamed with an according light protection screen in due time (please consider application time!).

Prior to or during a therapy session, the skin must be free of topical applications like, e.g. ointments; do not use sun protection on the skin that is to be treated. Certain pharmaceuticals increase the skin's UV-sensitivity, a fact you might want to discuss with your physician!

Moist skin

Moist skin is more receptive to UV radiation. Therefore the application on moist skin (e.g. after washing the scalp) may accelerate the success of the therapy.

Operation of Timer

At the onset of the treatment session, please make sure that the count-down timer is functioning properly (e.g. battery o.k.?)

Prior to starting a treatment session, plug the device into a suitable outlet, put on the protective goggles and keep the device switched on for approx. 5 min in order to achieve a stable UV-output.

Please set the provided count-down timer by pressing the according buttons „MIN“ for minutes and „SEC“ for seconds to the desired treatment time. Pressing the „Stop/Start“-button starts or interrupts the countdown for treatment time. By simultaneously pressing both „MIN“ and „SEC“ push buttons, the count-down timer resets to „00:00“.



Finding the right dose and treatment duration:

It is common nowadays to use the classification made by the American dermatologist Thomas Fitzpatrick in 1998 to define various skin types.

Skin type 1: pale white skin; blond or red hair - always burns, never tans

Skin type 2: fair; blond hair - usually burns, tans minimally (fair European type).

Skin type 3: fair, light-brown or brown hair, tans uniformly after repeated sun exposure (dark European type T).

Skin type 4: brown or black hair - rarely burns, always tans well (Mediterranean type)

Skin type 5: brown skin, very rarely gets a sunburn

Skin type 6: black skin, never gets sunburn

For vitiligo patients, the pigment-free skin areas to be treated are decisive for determining the skin type (lighter skin type).

Depending on the skin type, the following dosages are recommended, bearing in mind that these dosages are shown for the treatment of a single area and additionally for the entire scalp (6 times the area). Incorrect application can lead to overdose in the form of erythema (sunburn)! Special attention should be paid to the inner surfaces of the outer ears. They should not be treated for an extended period since they are extremely sensitive to UV light (UV protection see above).

The treatment times indicated are mere guide values; please consult with your dermatologist to determine your individual numbers. Upon reaching the highest dosage indicated for the according skin type, it is not sensible to increase further the dosage arrived at is to be maintained. Keep in mind, however, that excessive doses can lead to an acute aggravation of your skin condition (the so-called Köbner phenomenon).

Dosage recommendations and treatment times:

Skin type 1	Session	Dosage (mJ/cm²)	Time for single area (min:sec)	Time for complete scalp (6-fold area) * (min:sec)
	1	53	0:15	1:30
	2	105	0:30	3:00
	3	158	0:45	4:50
	4	210	1:00	6:00
	5	263	1:15	7:30
	6	315	1:30	9:00

	no increase	max. 788	max. 3:45	max. 22:30 **
Skin type 2	Session	Dosage (mJ/cm²)	Time for single area (min:sec)	Time for complete scalp (6-fold area) * (min:sec)
	1	70	0:20	2:00
	2	140	0:40	4:00
	3	210	1:00	6:00
	4	280	1:20	8:00
	5	350	1:40	10:00
	6	420	2:00	12:00

	no increase	max. 1050	max. 5:00	max. 30:00 **
Skin type 3	Session	Dosage (mJ/cm²)	Time for single area (min:sec)	Time for complete scalp (6-fold area) * (min:sec)
	1	88	0:25	2:50
	2	175	0:50	5:00
	3	263	1:15	7:30
	4	350	1:40	10:00
	5	438	2:05	12:30
	6	525	2:30	15:00

	no increase	max. 1,313	max. 6:15	max. 37:50 **
Skin type 4, 5 and 6	Session	Dosage (mJ/cm2)	Time for single area (min:sec)	Time for complete scalp (6-fold area) * (min:sec)
	1	105	0:30	3:00
	2	210	1:00	6:00
	3	315	1:30	9:00
	4	420	2:00	12:00
	5	525	2:30	15:00
	6	630	3:00	18:00

	no increase	max. 1,575	max. 7:30	max. 45:00 **

(*) For partial areas, reduce the treatment time accordingly.

(**) Longer exposure times can be divided between morning and evening sessions.

Conducting the Therapy

Only use the device in a dry environment. Always use the UV protective goggles provided and never look into the UV lamp with unprotected eyes! While you conduct the treatment, no other persons should be in the vicinity unless they are also protected from the UV radiation.



Always protect your eyes with the UV protective goggles!

Connect the device to a suitable power outlet, put on the protective goggles and leave the device switched on for approx. 5 min before each start of therapy to achieve stable UV emission. For this time, place the switched-on device on a suitable surface with the comb attachment facing downwards.

Now start the short-time timer with the previously set therapy duration. Please position the count-down timer where it is easily visible and acoustically perceivable for you; after counting down to zero, an acoustic signal will sound for approx. 30 seconds. You can turn it off by pressing any button. After pressing the Start/Stop button, the previously set or lapsed time will appear in the display again.

Now start the treatment of the affected skin areas. To treat a single area, place the UV comb flat on the corresponding skin area for the planned therapy duration. The hair parter or comb attachment facilitates reaching the hairy scalp skin and ensures the required treatment distance.



In case of the entire scalp the treatment is to take place slowly, distributed uniformly over the head and against the direction of hair growth. The comb attachment additionally serves here as a hair divider for reaching the hairy scalp.

The treatment should always be performed with the comb attachment mounted.



The treatment should be conducted **three to five times weekly**. The duration of the treatments depends on the type and severity of the skin disease. For the treatment of psoriasis and neurodermatitis, 20-25 sessions are usually sufficient until the skin symptoms have subsided. Vitiligo treatment can take considerably longer. If there is no success after 3 months at the latest, contact your treating physician to clarify a continuation of the treatment.

Therapy monitoring:

Following every treatment session, monitor the treated skin areas for therapeutic success as well as for possible side effects:

Should you discern side effects like a sun burn or painful change in the **diseased skin**, you have to reduce the dose for the next treatment by 40% and you may only continue with the treatment after the side effects have abated. If in doubt, consult your attending physician.

Should you discern side effects like a sun burn or painful change in the **healthy skin**, make sure to provide better protection for the next treatment like using sunscreen with a high protection factor or more carefully cover these areas with textiles.

Should you **not experience any successful therapy outcome** at all, gradually increase the dose as described in the tables. If you have reached the maximum dose according to your skin type and still do not notice any therapeutic effect, the service life of the UV lamp may be expired (see chapter 14). If in doubt, consult your attending physician.

When using the device by several patients, the comb attachment must be cleaned and disinfected before any patient change, in order to prevent infections between patients. The following disinfectants can be used for this purpose: Cleanisept®, mikrozyd® sensitiv liquid or Sani-Cloth™ Active.

For a sufficient disinfecting effect, the application instructions of the respective manufacturers, in particular the exposure times, must be observed.

12 Transport and Storage

Protect the UV comb during transportation from undesirable shocks; the UV lamp may be damaged (glass breakage). Store the therapy device in dry rooms and do not expose it to high temperatures.

13 Errors and Troubleshooting

UV lamp does not light - Check the outlet or use another outlet. Verify that the UV lamp is tightly inserted into the socket. First switch off the device and unplug the power cord.

If this did not fix the problem, contact the address specified in the manual.

14 Life cycle and service life

The service life of the UV comb is essentially dependent on the frequency of use. The average service life of the UV lamp is 500 hours. After this runtime, UV-radiation decreases. This also becomes evident by a decreasing therapy result. A defective or poor UV lamp may only be replaced by the manufacturer or professionals trained and authorized by the manufacturer. The use of a wrong UV lamp can cause burns. After replacing the UV lamp, the treatment duration has to be determined again (see chapter 10).

15 Maintenance and Repair

The UV comb is maintenance free. The commercial user is responsible for compliance with the required inspection resulting from national operator obligations and occupational health and safety regulations.

For repair ship the UV comb in the original packaging if possible. Make sure that the unit is protected from shocks and that the packaging is suitable for the selected shipping method. Do not forget to clean the unit and accessories before shipping.

16 Warranty

The manufacturer grants a 4-year warranty for the Saalux® UV comb from the date of delivery. (The manufacturer's terms and conditions apply in the version valid on the date of delivery).

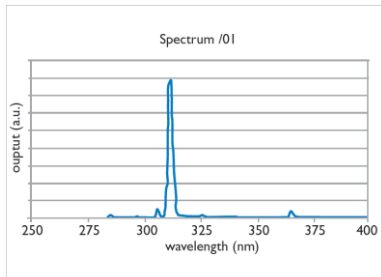
Any intervention on the therapy device by buyer or third parties renders the warranty claim void. Any defects or faults which are or might be caused by improper use or disregard for the „intended purpose“ or the instructions in the user manual result in the immediate loss of warranty claims against the manufacturer.

Categorically excluded from all warranty claims are wear parts or glass breakage (e.g. the UV lamp). Also excluded from the warranty is the UV-intensity of the UV lamp.

17 Electromagnetic compatibility

Medical-electrical devices are subject to special precautions regarding EMC. Please refer to appendix 1 for information on specific requirements for the electromagnetic environment.

18 Spectral Distribution of the Flow of Radiation



(Source: Medical Treatment Phototherapy, Philips)

19 Technical Data

UV-Output approx. 3.5 mW/cm² (on comb attachment level for continuous operation, local deviation +/- 20%)

Voltage/Frequency 230V/50 Hz

Power input 40 VA

Weight handheld unit 165 g

Weight base unit 450 g

Protection class II double insulated



Device classification BF



Photobiological classification Risk group 2 (according to EN 62471:2009)

UV safety distance 2 m for eyes (without UV goggles)
1 m for skin that is not to be irradiated

Requirements for:	Operation	Transport and storage
Temperature	+10°C to +30°C	-20°C to +70°C
Relative humidity	30 % to 70 %	< 90 %, non-condensing
Air pressure	700 hPa – 1060 hPa	700 hPa – 1060 hPa

20 Disposal instructions



The device may not be disposed of as domestic waste. Dispose of the device in a waste facility that accepts electronics/electrical appliances.

WEEE-Reg.-no. DE 39660475

21 Manufacturer contact information

If necessary, contact the manufacturer for assistance with regard to the use or maintenance of the Saalux device or to report unexpected operations or incidents. All serious incidents related to the device, as defined in Regulation (EU) 2017/745 on medical devices, shall be reported to the manufacturer and the competent authority of the Member State where the user and/or the patient is established.



Saalmann medical GmbH & Co. KG
Suedbahnstrasse 34
D-32547 Bad Oeynhausen
Germany


Internet	www.saalmann-medical.de
Mail	info@saalmann-medical.de
Phone	+49 (0)5731 25450 0
Fax	+49 (0)5731 25450 11

Appendix 1 – Electromagnetic compatibility

Electromagnetic emissions		
The Saalux® device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.		
interference emission	Compliance	Electromagnetic surrounding - Guidance
RF emission according CISPR 11	Group 1	The Saalux® device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission according CISPR 11	Class B	The Saalux® device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission according IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity			
The Saalux® device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.			
Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge max. ± 15 kV air discharge	± 8 kV max. ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients / bursts IEC 61000-4-4	± 2 kV for power supplies	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV for line(s) to line(s)	± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle 70 % for 25 cycles 0 % U_T for 250/300 cycles	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle 70 % for 25 cycles 0 % U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Saalux® device requires continued operation during power mains interruptions, it is recommended that the Saalux® device is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 61000-4-8			
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

Electromagnetic Immunity			
The Saalux® device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.			
Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Saalux® device, including cables, than the recommended separation distance (d in meter) calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V rms 150 kHz to 80 MHz within ISM bands and amateur radio bands	3 V rms 6 V rms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz	10 V/m	
Radiated RF according IEC 61000-4-3 in close proximity to wireless communication devices	according to IEC 60601-1-2:2014 Table 9	passed	(corresponds to a recommended safety distance of 0.3 m to the devices of the corresponding radio services)
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol 
NOTE: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			

Accessories und add-on products for the Saalux® UV comb:



UV-protective goggles – large version

For professional staff and wearer of glasses
(Art. no. 07-01-019-01)



Saalux® dandruff solution

Gentle removal of dandruff before starting the therapy:

- Faster therapy success
- Protection of healthy skin
- Clinically used recipe
- Vegetable base, without salicylic acid
- Easy to wash out

75 ml bottle with handy soft tip applicator
(Art. no. 07-03-001-03)

200 ml refill bottle
(Art. no. 07-03-001-02)

More information on: www.saalmann-medical.de
or order directly on: www.saalmann-medical-shop.de

A product of

SAALMANN®